UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

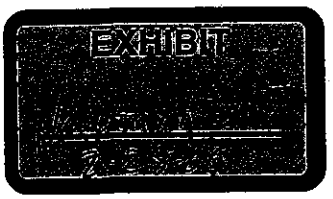
IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	M.D.L. No. 1456 Civil Action No. 01-12257-PBS Judge Patti B. Saris

REPORT OF INDEPENDENT EXPERT

PROFESSOR ERNST R. BERNDT

TO JUDGE PATTI B. SARIS

FEBRUARY 9, 2005



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I. INTRODUCTION

A. Qualifications

1. My name is Ernst R. Berndt. I am the Louis B. Seley Professor of Applied Economics at the Sloan School of Management, Massachusetts Institute of Technology. I have been a Professor of Applied Economics at MIT since 1980. From 1992 to 1995, I served as Area Head of the Applied Economics, Finance and Accounting faculty area at MIT's Sloan School of Management. I am also a Research Associate at the National Bureau of Economic Research, serve as Director of its Program on Technological Change and Productivity Measurement, and am an Adjunct Professor at the Harvard Medical School, Division of Health Care Policy. In 2004 I was named Co-Director of the Biomedical Enterprise Program, a joint degree-granting program at the Harvard-MIT Division of Health Sciences and Technology and the MIT Sloan School of Management. I am an elected Fellow of the Econometric Society, and have been awarded an honorary doctorate degree from Uppsala University in Sweden. My professional qualifications are described in my curriculum vitae, which is attached as Attachment A to this report.

2. In the last fifteen years, a major focus of my academic research has been on health economics and the economics of the pharmaceutical and biotech industries. I have studied the impacts of marketing (i.e., direct-to-consumer advertising, medical journal advertising, physician detailing, and physician sampling) on sales of pharmaceutical drugs, the pricing patterns of generic and brand name prescription drugs, and prescription-only to over-the-counter switches, among other topics. A great deal of my research involves issues of price measurement. I have studied or currently am studying: the treatment of brand and generic drugs in pharmaceutical price indexes; price indexes for the treatment of certain illnesses, particularly mental disorders;

and the reliability and appropriate interpretation of the U.S. Bureau of Labor Statistics' price indexes for medical services and products. I am currently studying the process by which promising medicines move from pre-clinical and clinical development phases through the U. S. Food and Drug Administration approval process, factors affecting the differential rates of diffusion of new medicines across different countries, and policies that would provide incentives to biotech and pharmaceutical companies to develop medicines for third-world diseases.

3. In addition to my academic research, from 1996 to 2000 I served as an appointed representative of the American Economic Association to the Economics Advisory Committee of the U.S. Census Bureau, and from 1999 to 200 as its Co-Chair. From 1991 to 2000 I served as a member of the Advisory Committee on Service Statistics at Statistics Canada. Between 1999 and 2001, I was a member of the U. S. Committee on National Statistics and the National Academy of Sciences, Panel on the Conceptual, Measurement and Other Statistical Issues in Developing Cost-of-Living Indexes. Between 2000 and 2004, I also served as Chair of the newly created U. S. Federal Economic Statistics Advisory Committee, an interagency committee jointly formed by the U.S. Bureau of Labor Statistics, the U. S. Census Bureau, and the U. S. Bureau of Economic Analysis. Recently I finished a two-year term as a review panel member for the Methodology, Measurement and Statistics program at the National Science Foundation. From October 2003 through June 2004 I served on an unpaid Intermittent Detail to the U. S. Food and Drug Administration, Office of the Commissioner.

4. Over the years, I have served as an expert on a number of health care litigation matters, retained by counsel for branded pharmaceutical and biotech firms, generic pharmaceutical manufacturers, by third party payors, and by the Federal Trade Commission.

B. Nature of Assignment and Terms of Engagement

5. In a telephone conference call on November 23, 2004 involving United States District Court Judge Patti B. Saris and Counsel for Plaintiffs and Defendants (in the case In Re Pharmaceutical Industry Average Wholesale Price Litigation, relating to 01-CV-12257-PBS and 01-CV-339, MDL No. 1456, Civil Action No. 01-12257-PBS), I confirmed my commitment to serve "as an independent expert on the pharmaceutical industry for purposes of the motion of class certification".[1] The subsequent Court Order specified:

> "The Court will meet privately with Professor Berndt following the presentations to discuss the topics of the report he will write about the pharmaceutical industry. If the Court submits questions to Professor Berndt, copies will be placed on the record. Professor Berndt will submit his report in late January. The parties agreed that the Court will be allowed to speak with Professor Berndt privately to clarify the contents of his report. If Professor Berndt provides information beyond what is in the record, he will supplement his report. Provisions for payment of Dr. Berndt by both sides shall be handled by Eric Green, not the Court."[2]

6. I am being compensated at my normal consulting rate of $525 per hour, plus reasonable out of pocket expenses, with Plaintiffs' counsel contributing a 33 percent share, and defendants' counsel a 67 percent share.[3] Invoices have been sent by Berndt Associates LLC to plaintiffs' and defendants' counsels on January 3, 2005, and February 1, 2005.

7. As stipulated in the Court Order, I attended Plaintiffs' tutorial on Monday, December 6, 2004, and Defendants' tutorial on Tuesday, December 7, 2005. I met very briefly with Judge Saris and her clerk, Benjamin Halasz, following the December 7, 2005 tutorial. I met with both

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[1] Court Order, email from Benjamin_Halasz@mad.uscourts.gov to berndt@rcn.com, dated Monday, January 24, 2005, containing transcription of Court Order entered November 23, 2004. Hereafter I refer to this as "Court Order".
[2] Court Order, *supra.*
[3] Letter from D. Scott Wise and Steven Berman to Dr. Ernst R. Berndt, Berndt Associates, Inc., dated November 18, 2004. Eric Green, Resolutions LLC, is a mediator.

Judge Saris and Mr. Halasz for about an hour on Monday, December 13, 2004, discussing in general the topics I would be addressing in my report. I met with Mr. Halasz for about 90 minutes on Thursday, January 27, 2005, and discussed with him the portions of the report I had preliminarily drafted, as well as topics and issues I planned to address in the final version of this report. Although I brought with me to that meeting and shared with Mr. Halasz a hard copy of my incomplete draft report, Mr. Halasz returned the copy to me as I left. The Court has therefore not had in its possession either a hard copy or electronic version of that incomplete draft report. I have had several email exchanges with Mr. Halasz involving general questions on meeting logistics, the legal status of certain allegations, and the Corrected Amended Master Consolidated Class Action Complaint.

C. Interpretation of My Assignment

8. This litigation has generated a voluminous amount of documentation. Judge Patti B. Saris has described the litigation as a "massive proposed class action".[4] I understand my assignment as an independent expert is to provide context, background, literature citation and analysis to assist the Court in efficiently interpreting information provided it by counsel for Defendants and counsel for Plaintiffs. I am also asked to outline what additional, if any, potentially material information has not been presented to the Court, particularly in the context of class certification issues involving commonality and typicality. I have approached this assignment as an academic endeavoring to be of service to the Court in undertaking a substantial research project, first attempting to understand the background, then delving into details, and finally, writing up the results of the analyses. That is the approach I have taken, albeit on an

[4] *Memorandum and Order,* United States District Court, District of Massachusetts, In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D. L. No. 1456, Civil Action No. 01-12257-PBS, United States District Judge Patti B. Saris, February 24, 2004, p. 1.

accelerated timetable. While my primary focus in this report is not on issues of merit, my background discussion and critiques in some instances may be interpreted as crossing that line.

D. Information Considered

9. In undertaking my analyses, I have considered information from a wide variety of sources. As appropriate, I reference these in the report when I rely on them directly. The information I considered includes documents provided through legal filings and the discovery process; tutorials presented to the court; third party data sources and industry reports; academic papers, government reports and scholarly writings; and research reports from investment analysts and industry trade publications.

E. Structure of the Report

10. I begin in Section II by providing a brief overview of Plaintiff's allegation, the role of AWP, as well as a summary of the methodology employed by Plaintiff's Expert Dr. Raymond S. Hartman. In Section III I discuss extensively the origin, evolution and persistence of AWP and the "spread" between AWP, the wholesale acquisition price ("WAC"), and actual acquisition prices. I do this separately for brand name/single source self-administered drugs, generic/multisource self-administered drugs, and physician-administered drugs, pointing out their similarities and especially their differences.[5] In this Section I also review public documents describing the discounts off AWP obtained by government and private sector payors, consider why it is that confusion concerning what AWP measures continues and persists, and briefly note other uses of AWP.

11. In Section IV, which constitutes a substantial portion of the report, I consider a variety of issues involving competition, price transparency, information flows and PBM management of

[5] While I understand that precise definitions of brand, generic, single source and multi-source drugs are complex, unless I state distinctions explicitly, for the purposes of this report I will largely overlook those complications.

purchases of self-administered drugs. In Section V I consider competition, price transparency, information flows and the rather different environment in which purchases of physician-administered drugs are managed. Finally, in Section VI I consider a number of specific issues dealing with class certification, and comment on the proposed methodology of Plaintiff's Expert Dr. Raymond S. Hartman.

II. OVERVIEW

A. The Complaint

12. In what Judge Patti B. Saris has called a "massive proposed class action", Plaintiffs have alleged that by setting and facilitating the publication of "average wholesale prices", forty-two pharmaceutical companies have fraudulently overstated actual acquisition costs for many prescription drugs, resulting in inflated payments for such drugs by consumers and beneficiaries of the federal Medicare Part B program (through coinsurance payments), private health and welfare plans, health insurers, self-insured employers and other end-payors for prescription drugs.[6] Plaintiffs have identified 321 drug entities (designated AWPIDs), including self-administered and physician-administered, branded (single-source and multi-source) and generic (multi-source), with allegedly inflated prices.[7] Defendant's expert Steven J. Young calls the proposed class size "enormous", noting that in 2003 there were over 350 Health Plans in the US covering over 197 million lives, entering into "innumerable" contracts involving many of the approximately 497,852 physicians, 55,001 pharmacies and 60 pharmaceutical benefit

[6] *Memorandum and Order,* United States District Court, District of Massachusetts, In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D. L. No. 1456, Civil Action No. 01-12257-PBS, United States District Judge Patti B. Saris, February 24, 2004, p. 1.
[7] *Memorandum and Order,* February 24, 2004, *supra,* pp. 1-2.

management firms.[8] Plaintiffs' expert Dr. Raymond S. Hartman simply calls the proposed class "large".[9]

13. In their December 17, 2004 amended motion for class certification, Plaintiffs have named end-payor classes as follows: (i) physician-administered drugs class (Medicare Part B co-pay and private system physician-administered drugs); (ii) self-administered and specialty pharmacy drugs class (third-party and co-payor class for self-administered drugs), further subdivided into (iia) brand name sub-class and (iib) generic sub-class; (iii) RICO class for self-administered and specialty drugs, further divided into (iiia) brand name sub-class and (iiib) generic sub-class. The proposed class period is January 1991 to the present.[10]

B. The Role of AWP

14. To knowledgeable industry observers, it has long been widely understood that in the US pharmaceutical industry the term "average wholesale price" (hereafter, "AWP") is a misnomer: it is not a measure of prices generally paid by wholesalers to manufacturers, it is not a measure of prices frequently paid by retail or mail order pharmacies to wholesalers, nor is it some average of these. I will document this below.

15. At least since the beginning of the widely publicized "Brand Name Drug Litigation" in 1994, it has been common knowledge among industry observers that brand pharmaceutical firms typically sell self-administered single-source drugs to wholesalers at a price known as "wholesale acquisition cost" ("WAC") that in most cases is 16.67% to 20% less than AWP; this

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[8] *Declaration of Steven J. Young In Opposition to the Plaintiff's Motion for Class Certification*, United States District Court, District of Massachusetts, In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D. L. No. 1456, Civil Action No. 01-12257-PBS, United States District Judge Patti B. Saris, October 25, 2004, pp. 8-9.
[9] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification,* United States District Court, District of Massachusetts, In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D. L. No. 1456, Civil Action No. 01-12257-PBS, United States District Judge Patti B. Saris, December 16, 2004, p. 3.
[10] *Plaintiffs' Amended Motion for Class Certification*, United States District Court, District of Massachusetts, In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D. L. No. 1456, Civil Action No. 01-12257-PBS, United States District Judge Patti B. Saris, December 17, 2004, pp. 3-4.

implies that AWP is typically 20% to 25% greater than WAC.[11] Moreover, using various rebates and chargeback policies, brand pharmaceutical manufacturers have offered a variety of discounts to health care providers and pharmaceutical benefit management ("PBM") firms, frequently expressed as "AWP – x%" or "WAC ± y%", in return for favorable placement of their drug on the client's formulary, meeting market share or volume targets, and/or attaining other contractually specified goals.[12] In turn, providers and PBMs have contracted with pharmacy networks, reimbursing them for dispensing drugs, generally employing contractual terms such as "AWP – z%" plus a dispensing fee, and perhaps administrative fees.

16. If a contract involving branded single-source self-administered drugs were specified in terms of WAC rather than AWP, in most cases it has been straightforward to convert it to AWP terms, given the largely predictable relationships between AWP and WAC (although this AWP-WAC relationship is considerably more complex and variable with multisource brand and multisource generic drugs).[13] In this way, even though industry observers and academics have quipped that AWP stands for "Ain't What's Paid" rather than "Average Wholesale Price",[14] it is nonetheless the case that AWP has served as a reference or focal point, an industry standard for baseline reimbursement, and as such a fictional benchmark price from which discounts are frequently specified, directly or indirectly. Hence, as Plaintiffs' Expert Dr. Raymond Hartman has written, "AWP is interpreted by the industry as a measure of the underlying structure of drug

[11] *In re Brand Name Prescription Drugs Antitrust Litigation*, Case No. 94 C 897; MDL No. 997, United States District Court for the Northern District of Illinois.
[12] Laurie P. Cohen and Elyse Tanouye, "Bitter Pill: Drug Makers Set to Pay $600 Million to Settle Lawsuit by Pharmacies – Retailers Object to Practice of Granting Discounts To HMOs but Not Them – Eight Defendants to Fight On", *Wall Street Journal*, 18 January 1996, p. A1.
[13] A branded drug can be either a patent-protected single source drug, an innovator branded drug that has lost patent protection and faces generic competition, or in some cases, a patent-protected drug sold under distinct brand names, or in even rarer cases, a "branded generic" that is a multisource drug promoted by its brand rather than chemical name. Multisource drugs include both brands that have lost patent protection and generic drugs.
[14] Although "AWP: Ain't What's Paid" was prominently displayed in the 1996 Barron's article (Bill Alpert, "Hooked on Drugs: Why do insurers pay such outrageous prices for pharmaceuticals?", *Barrons*, June 10, 1996, 3 pp), as I note below, this association with AWP has an earlier history.

prices,"[15] and "The AWP, or its formulaic equivalent the WAC (wholesale acquisition cost), is interpreted by industry as the signal for the underlying structure of list and transaction prices for almost all drugs."[16]

17. Given the widespread knowledge that AWP has long overstated actual transactions prices among manufacturers, providers, PBMs and retailers, as I understand it, in this litigation Plaintiffs are alleging that while payors understood that discounts off AWP were pervasive, certain manufacturers have covertly manipulated further the AWP and actual transactions cost structure of drug prices, resulting not just in an inflated AWP, but in an "artificially inflated"[17] or "grossly inflated"[18] AWP, which in turn allegedly damaged certain end-payer classes. These damages depend in large part on the "spread" between AWP and the actual average selling price ("ASP") in the case of manufacturer contracts with PBMs, or between AWP and the actual average acquisition costs ("AAC") in the case of sales by manufacturers to distributors or health care providers.[19] As examples, Plaintiffs call attention to recent guilty pleas and settlements involving physician-administered (not self-administered) drugs such as Lupron (an anti-cancer agent, marketed by Abbott Laboratories, Takeda Chemical Industries, Ltd., and TAP Pharmaceutical Products, Inc.) and Zoladex (a slightly different anti-cancer agent, marketed by AstraZeneca Pharmaceuticals LP)[20]. I note that these guilty pleas involved defendants' actions

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[15] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, p. 1.
[16] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, p. 3.
[17] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, p. 6; *Plaintiffs' Memorandum In Opposition to Defendants' Motion to Strike the Hartman Declaration*, December 17, 2004, p. 10.
[18] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, p. 72.
[19] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, p. 6. As I note later, this is but one definition of "spread".
[20] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, p. 6, fn. 18; also p. 8, and p. 13 fn. 32.

of providing free samples to physicians, and encouraging physicians to bill Medicare at the published AWP.[21]

18. In assessing whether the proposed end-payer classes were damaged, Plaintiffs' Expert Dr. Hartman proposes first to compute the spreads between AWP and ASP "for drugs unaffected by the scheme and fraud", and then use these as "yardsticks" in comparison with spreads observed "for the drugs subject to this litigation". In cases where he determines the latter spreads are larger than the former, Dr. Hartman proposes to employ his yardsticks along with mathematical and algebraic formulae "to determine the spread that would have been used for the affected drugs but-for the wrongful scheme", thereby determining "the overall class-wide injury and damage for each drug".[22]

19. Because there are numerous types of transactions among different parties in the drug distribution system (among manufacturers, wholesalers, pharmacies, pharmaceutical benefit managers ("PBMs), and third party payors (including health plans, insurers, and employers), there are many alternative concepts of "spreads". I will try to distinguish these as I proceed in this report. For example, at the Plaintiffs' tutorial before Judge Saris on December 6, 2004,

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[21] In the United States District Court for the District of Massachusetts, Eastern Division, *United States of America v. TAP Pharmaceutical Products, Inc., Criminal Action No. 01-CR-10354-WGY, Sentencing Memorandum of the United States,* the civil and criminal resolution was limited to TAP's violation of the Prescription Drug Marketing Act, for losses suffered by Medicare and Medicaid as a result of TAP's fraudulent drug pricing schemes and sales and marketing misconduct, and for losses suffered by Medicaid for TAP's failure to provide "best price" for Lupron. There is no explicit charge of inflating or artificially inflating AWP, although TAP's ability to change AWP at any time is acknowledged. In United States District Court, District of Massachusetts, MDL No. 1430, Master File No. 01-CV-10861-RGS, *In Re: Lupron Marketing and Sales Practices Litigation, Memorandum and Order on Defendants' Motion to Dismiss Corrected Consolidated Amended Class Action Complaint and Second Amended Consolidated Complaint*, Judges Stearns cites Plaintiffs' allegation that defendants' (including TAP) conspired "to artificially inflate the price of the drug Lupron" (p. 1). The Judge later states that " defendants trumpeted a lie by publishing the inflated AWPs, knowing (and intending) them to be used as instruments of fraud" (p. 18), and comments that "there is a difference between a sticker price and a sucker price" (fn. 19, p. 20). In the case of Zoladex, press releases on AstraZeneca's guilty plea to criminal charges of fraud in the marketing and pricing of Zoladex variously refer to "deliberately inflating" the reported AWP (see http://www.ago.state.ma.us/sp.cfm?pageid=986&id=1050, p. 1, accessed 12/31/04), and "improperly setting and reporting its price" (see http://www.astrazeneca.com/pressrelease/500.aspx , p. 1, accessed 12/31/04).

[22] *Plaintiffs' Memorandum In Opposition to Defendants' Motion to Strike the Hartman Declaration*, December 17, 2004, p. 3.

Professor Meredith Rosenthal discussed another concept and measure of "spread" that for a PBM referred instead to what the PBM charged the payor/insurer (e.g., AWP – f% + administrative fees) minus what the PBM reimbursed the pharmacy (e.g., AWP – g% + dispensing fee + administrative fee), in which case the PBM "spread" equaled g% - f% + differential fees.[23] Professor Rosenthal also appears to assert that for the self-administered drug classes, each class member must have a contractual relationship with a PBM.[24]

III. THE ORIGINS, EVOLUTION AND PERSISTENCE OF AWP AND "SPREAD"

A. Brand Name/Single Source Self-Administered Drugs

20. To understand today's interactions among drug manufacturers, wholesalers, retailers and PBMs, it is informative to consider briefly the history of how AWP, and differences between AWP and WAC, came into being, along with the important role of information and communications technology in affecting distribution costs and industry structure. Unfortunately, much of this history is anecdotal and oral, known by the legions of economists, industry consultants and attorneys involved in the now legendary Brand Name Drug Litigation involving branded (typically patent-protected) self-administered medications (orals, topicals, inhalants, self-injectables and other miscellaneous products). Interestingly, in the context of this litigation a hint of this history is given in the deposition of AstraZeneca's John R. Freeberry, on which I will comment further below.[25]

21. To the best of my knowledge, the first widely circulated written discussion of the AWP history is that by Professor E. M. (Mick) Kolassa, who in 1997 authored a textbook, *Elements of*

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[23] *Written Tutorial of Meredith Rosenthal*, Ph.D. presented before Judge Patti B. Saris, United States District Court for the District of Massachusetts, December 6, 2004, p. 16.
[24] *Written Tutorial of Meredith Rosenthal*, Ph.D., supra, p. 12.
[25] Deposition of John Richard Freeberry, May 20, 2004, pp. 168-172. These pages are reproduced as Exhibit 2 in the *Declaration of Steve W. Berman in Support of Plaintiffs' Reply to AstraZeneca Pharmaceuticals LP's Individual Memorandum in Opposition to Class Certification*, December 17, 2004.

Pharmaceutical Pricing.[26] Substantial portions of the material in that text overlap, however, with paragraphs in an earlier 1994 peer-reviewed article,[27] as well as with presentational material prepared for previous marketing consulting/research seminars conducted by Professor Kolassa.[28] Kolassa [1997] begins by defining AWP as follows:

> "Neither an average price nor a price charged by wholesalers, this figure is a vestige of earlier times. Few, if any, wholesalers even consider AWP today when pricing their prescription products. It is, however, commonly used by retailers and others who dispense medications as the basis for many pricing decisions. Due to its availability from many sources, the AWP is often used as a surrogate for actual prices when studying prescription price trends".[29]

22. In Kolassa [1994a], the original *raison d'être* for AWP and for the now infamous common 20%-25% "spreads" between wholesalers' acquisition and retail pharmacy acquisition costs of branded self-administered drugs is recounted. Recall that during the 1980s, following the pioneering practices of WalMart and other "superbox" retailers, implementation of information and communications technological developments significantly impacted the rationalizing of wholesaler-retailer distribution logistics, the monitoring of transactions in real time, and the management of inventory, reducing costs and in the process leading to the demise of many small retail and wholesale firms. These phenomena also occurred in the context of pharmaceuticals.[30] Despite its length, the following quote from Kolassa [1994a] is illuminating:

> "The AWP, the most common figure used for drug price comparisons, is a vestige of a drug distribution system that disappeared in the early 1980s. Prior to that

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[26] E. M. (Mick) Kolassa, *Elements of Pharmaceutical Pricing*, Binghamton, NY: The Pharmaceutical Products Press, 1997.
[27] Mick Kolassa, "Guidance for Clinicians in Discerning and Comparing the Price of Pharmaceutical Agents", *Journal of Pain and Symptom Management*, 9(4), May 1994: pp. 235-243. Hereafter I denote this reference as Kolassa [1994a].
[28] See, for example, *Elements of Pharmaceutical Pricing: A two-day marketing research seminar*, Radisson Hotel & Suites, Fairfield, NJ, August 9-10, 1994. Hereafter I denote this reference as Kolassa [1994b].
[29] Kolassa [1997], *supra*, p. 30.
[30] For another discussion on the impacts of information and communications technology on wholesale-retail interactions in the pharmaceutical industry, see "Computers as Agents of Change" (pp. 61-65) and "Retailing Reorganized" (pp. 65-67) in John T. Fay, Jr., "The Wholesaler", ch. 12 in Mickey C. Smith, ed., *Principles of Pharmaceutical Marketing*, Third Edition, Philadelphia: Lea & Febiger, 1983.

time, there were several hundred small, independent drug wholesalers, each operating regionally. Due to the inefficiencies of such a fragmented system, the operating costs were quite high. The average markup above cost by these wholesalers to their retail customers, primarily pharmacies, was 20% to 25%, depending on manufacturer. The manufacturer differences were due to the fact that, while most pharmaceutical manufacturers used a wholesaler-only method of distribution to the retail class of trade, a significant number of large firms had invested in their own distribution networks and preferred 'direct' sales over the use of wholesalers. By convention, wholesalers added 20% to the price of products from companies following a wholesaler-only policy while adding 25% to the prices of products from those companies who chose to 'compete' with the wholesalers. At that time, virtually all pharmaceutical companies sold products directly to hospitals that did not use wholesalers. As a result, less than one-half of the pharmaceutical products sold in the United States were handled by drug wholesalers in the early 1970s. {Footnote in Kolassa [1994a] omitted.}

In the late 1970s and early 1980s, several wholesale drug companies began to acquire smaller competitors. At that time, a few companies expanded significantly, many becoming national in scope. As a result, there are fewer than 90 separate wholesaler drug companies today, with more consolidations expected in the next few years. The expansion of major firms also concentrated competition. Prior to this consolidation, most wholesalers had little or no competition, so there was little pressure to reduce their markups. The consolidation in the industry resulted in major wholesale companies competing for the same business. The net effect was price competition.

This expansion of major wholesalers led to greater efficiencies as the wholesalers adopted more sophisticated inventory control systems, and to the expansion of services offered to retail and hospital customers. Large wholesalers then used their competitive advantages to gain and keep new customers. The utilization of wholesalers increased substantially during this period, resulting in the wholesalers' handling of over 80% of prescription product sales by 1987. {Footnote in Kolassa [1994a] not reproduced here.}

Additionally, during the 1980s, the prices charged by the manufacturers began to increase. This allowed the wholesalers to practice arbitrage, buying drugs in anticipation of price increases, then selling their inventory at the new, higher prices. These combined forces brought the average wholesale markup today to roughly 2.5%, significantly lower than the markup implied by the published AWP.

Price-reporting services, however, still rely upon the AWP as their primary figure, because many companies publish only that figure (usually called the "suggested price to pharmacy"). A recent move by several manufacturers, however, is to publish only their own list prices, refusing to offer the traditional AWP figure. This has been done, reportedly, because many name-brand drug makers feel the

> AWP unfairly distorts their prices and results in competitive disadvantages. The AWP, although not the cost paid by retailers, still provides the basis for much retail pharmacy pricing, with retailers euphemistically referring to the difference between their actual cost and the AWP as 'earned discount'. This tradition is so ingrained that a retailer that sells a product at AWP, which is 12%-18% above their cost, refers to this price as a 'loss leader'."[31]

Kolassa summarizes this discussion by stating, "Within pharmacy circles, the definition of AWP, it is joked, is 'Ain't What's Paid.'"[32]

23. The evolution of the AWP – WAC "spread" for branded self-administered pharmaceuticals is therefore, as best I can tell, quite understandable, and apparently not the result of any sinister or nefarious conspiracies. Moreover, since AWP was publicly known, it served as a convenient focal point metric for contractually specifying various reimbursements, and for efficiently adjudicating pharmacy transactions electronically.

24. Why this "spread" practice has continued long after its underlying rationale has largely disappeared is a bit puzzling, but is I believe understandable and plausible. Given the AWP – WAC history, retail pharmacies plausibly continued to expect their acquisition costs to be 20-25% below AWP, and thus in their contracts with third party payors and PBMs, retailers generally expected to be reimbursed at 10-15% below AWP. In such a context, one can understand that a single manufacturer marketing a newly FDA approved drug would find it quite challenging if not impossible to successfully set an AWP that was only, say, 2-5% above the WAC, for with that small a differential, retailers would be unable to recover their acquisition costs, unless they renegotiated and rewrote contracts with PBMs and other third party payers (such contracts typically applied a uniform percent discount across all single source branded self-administered drugs, regardless of therapeutic class).[33]

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[31] Kolassa [1994], *supra,* pp. 236-237; much of this material is reproduced in Kolassa [1997], *supra,* pp. 33, 35-36.
[32] Kolassa [1994a], *supra,* p. 237.
[33] The percent figure typically varied, however, depending on whether the drug was a brand or generic.

25. An example may help to clarify this. Suppose that the AWP of Drugs X and Y is a common $100, and that their WAC is a uniform $80 (the AWP in both cases is 25% above the WAC). Suppose further that the pharmacy's acquisition cost for both drugs is equal to WAC, which is a reasonably decent approximation to actual retail pharmacy acquisition costs;[34] hence the pharmacy's actual acquisition cost ("AAC" for the moment) equals $80. Finally, suppose that in its contract with a health plan or PBM, the pharmacy is reimbursed for all branded self-administered drugs at AWP – 15%.[35] This means that for each prescription of Drug X or Drug Y dispensed to a beneficiary of the health plan, the pharmacy is reimbursed at $85 (with an AWP of $100, AWP – 15% is $100 - $15 = $85). Notice that in this example, the pharmacy's gross margin on each prescription is $5 (it is reimbursed $85 by the health plan/PBM, and acquires the drug for $80).

26. Now suppose that for whatever reason, the manufacturer of Drug X wants to bring AWP much closer into alignment with the WAC, and instead of setting an AWP spread of 25% over WAC, it seeks to reduce the premium to 10%. This reduces the AWP for Drug X from $100 to $88 (110% of the $80 WAC price). Now, with reimbursement contracts between health plans/PBMs and retail pharmacies unchanged, the pharmacy will continue to be reimbursed for all branded self-administered drugs at AWP – 15%. Hence, the pharmacy would continue to be reimbursed at $85 per prescription for Drug Y. While the pharmacy would also still be reimbursed for Drug X at 85% of AWP, now, however, the AWP will have fallen from $100 to $88, implying that reimbursement from the health plan/PBM would only be 85% of $88, or $74.80. With an unchanged acquisition cost of $80 for both Drugs X and Y, the pharmacist

[34] See, for example, Congressional Budget Office, *Medicaid's Reimbursements to Pharmacies for Prescription Drugs*, December 2004, p. 8, fn. 12; Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Abt Associates Inc., Cambridge, MA, August 30, 2004, p. 14.
[35] For simplicity, here I ignore dispensing fees and other administrative charges/fees.

would lose on each prescription for Drug X (receiving $74.80 in reimbursement but having an $80 acquisition cost, implying a $5.20 loss on each Drug X prescription). The pharmacy would, however, continue to earn a $5 gross margin on Drug Y. Clearly, the manufacturer of Drug X would find it difficult to sell its drug to the retail pharmacist, due to the lower AWP – WAC spread policy it implemented only for Drug X.

27. Recognizing this problem with retail pharmacies, the manufacturer of Drug X might try to arrange for unique treatment from health plans/PBMs contracting with pharmacies. Specifically, the manufacturer might attempt to have all contracts between all pharmacies and health plans/PBMs rewritten so that, unlike all other branded self-administered drugs reimbursed at AWP – 15%, Drug X would be reimbursed at AWP – 3.5%.. With this new reimbursement formula, the pharmacies' gross margins for Drug X would continue to be about $5 (or very slightly smaller at $4.92), thereby making neutral or roughly equal the reimbursements received by the pharmacy for Drug X and Drug Y.[36] However, precisely because of the efficiency advantages of common contracting terms and common algorithmic formulas in processing pharmacy claims electronically, the health plans/PBMs and pharmacies would likely strongly resist such costly special treatment of Drug X. Even if the manufacturer were a very, very large manufacturer with a large portfolio of branded self-administered drugs, and even if it proposed reducing the spread on all its products, not just Drug X, it is very likely that the proposed policy change would be a failure commercially, and that pharmacies and health plans/PBMs would offer strong resistance.[37]

[36] In this example, for an AWP of $88, AWP – 3.5% is $84.92. With an acquisition cost of $80, the pharmacy gross margin would be $4.92. A manufacturer to pharmacy pricing policy of AWP – 3.40909% would yield an almost perfectly neutral gross margin of $5 for Drug X, identical to that for Drug Y.

[37] I am aware of course that Defendants' reducing the spread between AWP and actual acquisition costs is not the behavior alleged by Plaintiffs in this litigation.

28. In the current litigation, AstraZeneca deponent John R. Freeberry apparently refers to such an experience when in about 1994, the newly formed Astra Merck joint venture had to deal with two different legacies from its parent companies, one involving an AWP 20% greater than WAC, and the other a 25% differential. Astra Merck apparently sought to change the AWP – WAC differential from 25% to 20%, and may have even considered a more dramatic pricing policy change involving publication of an AWP that even more closely approximated average transaction price. According to Freeberry:

> " the reason we couldn't really do that was because pharmacists are reimbursed on a set contract for all of their brands. That's our understanding of it. So they're reimbursed an AWP minus 10 percent, minus 15 percent.
>
> So if we set our AWP at 2 percent, obviously they would lose money, and they wouldn't use our products. So we have to be consistent with the industry standard in order for the – to be – competitively fair."
>
> Q: "When you're referring to having changed the whole industry, are you referring to anyone other than the retailers and what you've just described with retailer contracts?"
>
> A: "I'm referring to the whole reimbursement process for the pharmacists. All these contracts are based on AWP price to the retailers."[38]

29. These observations suggest the very plausible hypothesis that even though the original rationale supporting the AWP – WAC or AWP – ASP differential for brand name/single source self-administered drugs had largely disappeared by the 1980s, there were no incentives for any one manufacturer to change the system pricing structure, and indeed, the incentives that did exist were perverse in that unilaterally publishing more accurate AWP prices would be unprofitable and therefore unsustainable for any one manufacturer.

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[38] Deposition of John Richard Freeberry, May 20, 2004, pp. 175-176 (quotation); this line of questioning begins earlier, on page 170. These pages are reproduced as Exhibit 2 in the *Declaration of Steve W. Berman in Support of Plaintiffs' Reply to AstraZeneca Pharmaceuticals LP's Individual Memorandum in Opposition to Class Certification*, December 17, 2004.

30. Moreover, even if each company unilaterally decided to participate in a coordinated industry-wide agreement to change AWP/WAC pricing practices, such actions might invite antitrust scrutiny and challenge from the U.S. Department of Justice. Such antitrust concerns apparently occurred in the early 1990s when pharmaceutical manufacturers considered (and then rejected) the idea of mutually pledging to keep brand name drug prices from rising more rapidly than the Consumer Price Index.[39] In the current litigation, I note that in fact related antitrust allegations have been made by Plaintiffs involving participating defendants in the Together Rx Card program.[40]

31. In summary, for brand name/single source self-administered drugs, while the underlying rationale supporting a 20-25% spread between AWP and WAC has long disappeared, manufacturers and retailers appear to be locked in to this practice. In the jargon of economics and game theory, what we observe is a Nash equilibrium in which for all players AWP exceeds ASP and WAC. There is no incentive for any brand name manufacturer of self-administered single-source drugs to align its AWP to a level much closer to WAC.

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[39] Following Merck's 1990 announcement of a voluntary commitment to limit annual prices increases to no more than growth in the overall Consumer Price Index ("CPI"), several other pharmaceutical firms followed suit. In 1993 the Pharmaceutical Manufacturers Association ("PMA") requested a business review by the U.S. Department of Justice of a program it proposed to implement, whereby member companies would commit to limiting annual price increases at rates not to exceed growth in the CPI, subject to independent audit. On October 1, 1993, Assistant U.S. Attorney General Anne Bingaman responded for the Department of Justice, opining that "the Department currently intends to bring suit to challenge the program if PMA and its members go forward with this proposal". Bingaman went on to write that " the proposed program would violate the antitrust laws. An agreement among independent competitors that interferes with free and open price competition by restraining individual pricing decisions is a per se violation of the Sherman Act. The per se rule has been applied to agreements among competitors that fix or set the prices at which goods or services are sold as well as agreements that set price-related terms but not the specific price at which transactions occur." Online at http://www.usdoj.gov/atr/public/busreview/0772.htm, pp. 1,2.

[40] As I understand it, in the current litigation, the Nationwide End Payor Together Card Class Plaintiffs allege conspiracy and Sherman Act violations when defendants allegedly moved almost simultaneously to a common 25% spread between AWP and WAC for drugs covered by the Together Rx Card. See *Corrected Amended Master Consolidated Class Action Complain Modified Per the Court's Instruction at the November 21, 2003 Hearing with Amgen Amendments*, United States District Court, District of Massachusetts, In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D. L. No. 1456, Civil Action No. 01-12257-PBS, United States District Judge Patti B. Saris, December 5, 2003, Counts V through X, pp. 280-304.

32. An alternative potential source of change in bringing about more accurate public average prices could have been the federal government. While over the years the federal government has purchased a limited number of drugs in its Medicare Part B program, together with the states it currently pays for a much larger amount of drugs through the states' Medicaid programs. I will return to the federal government's role as possible agent of change in bring published prices closer to actual acquisition prices in sub-section C below.

B. Generic/Multisource Self-Administered Drugs

33. During the 1970s and 1980s when wholesaler-retailer interactions were revolutionizing electronic transactions, generic drugs played a relatively minor role, not only in numbers, but also in dollar sales proportions. While the share of prescriptions of self-administered drugs dispensed generically has increased substantially in the last two decades, their dollar share has remained relatively modest, typically in the range of 10%-20%.

34. According to a 1985 Federal Trade Commission study, in 1980 31% of prescriptions were written for single-source drugs, while 69% were written for multi-source drugs. However, among the 69% written for multi-source drugs, 55% had the brand name written on the prescription, while the remaining 14-15% specified the generic (not brand) name. Almost all prescriptions written with the brand name were dispensed as written (52% of the 55%), and only for a small portion (3% of the 55%) was a generic substituted for the brand.[41] The total proportion of prescriptions dispensed as generics was therefore about 18% (15% written as generic, plus 3% substituted with generic).

35. Since at that time the average retail prescription price of a generic was about 75% of that for a brand ($6.22 vs. $8.22), as a proportion of generic plus retail drug revenues, the generic

[41] Alison Masson and Robert L. Steiner, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws*, Staff Report of the Bureau of Economics, Federal Trade Commission, October 1985, p. 26, Figure 2-1. Washington DC: U. S. Government Printing Office.

dollar share in 1980 was about 14%.[42] Relatively speaking, therefore, in 1980 generics were not that important at the retail level, although even then the average retail gross margin was larger than that for brands, not only proportionally, but even in absolute terms.[43]

36. Several years later, at the time Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the Hatch-Waxman Act), the generic share of prescription units was essentially unchanged at 18.6%. In the years that followed, two offsetting trends occurred that significantly affected retail pharmacies and the sources of their profitability.

37. First, the growing effects of states' mandatory generic substitution laws, along with much greater entry by generic manufacturers facilitated in part by the Hatch-Waxman Act, resulted in the proportion of total prescriptions dispensed as generics increasing sharply – from 18.6% in 1984 to 32.0% in 1989, 41.6% in 1994, and 47.1% in 1999.[44]

38. Second, the gap in average retail price per prescription between brand and generic drugs increased substantially for retail pharmacies, implying that even though the proportion of prescriptions dispensed as generics increased sharply after 1984, the proportion of retail pharmacy prescription drug revenues attributable to generics did not rise by nearly as much. For example, while in 1980 the relative average brand price was about 32% larger than that for a generic prescription ($8.22 vs. $6.22), by 1994 this gap increased to more than 200% ($53.80 vs.

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[42] In Masson and Steiner, *supra*, Table 3-1, p. 36, the average retail price of a brand prescription in 1980 is reported as $8.22, while that for a generic is $6.22. Multiplying these per prescription prices by their sales proportions implies that of the $7.8 billion total pharmacy revenues, about $1.12 billion, or 14.2%, were attributable to generics.
[43] Masson and Steiner, *supra*, Table 3-1, p. 36, report that the absolute gross margins per prescription were $3.35 (brands) and $3.57 (generics), with invoice costs being $4.86 and $2.65, respectively. As a proportion of the average retail price, therefore, the brand gross margin was about 41%, while for generics at 57% it was larger.
[44] Pharmaceutical Research and Manufacturers of America, *2000 Industry Profile*, PhRMA, Washington DC, 2000, Figure 5-7, p. 69.

$17.40).[45] Between 1980 and 1994, the average retail single source brand prescription price increased by about a factor of six, while that for a generic increased by only slightly less than a factor of three. As a proportion of retail pharmacy sales, the generic comprised 17.3% of revenues, only slightly larger than the 14.2% in 1980.[46]

39. Viewed from the vantage of third party payors, while the generic share of total prescription drug expenditures continued to be relatively small at 14-17%, from the point of view of retail pharmacies the proportion of gross profit margins attributable to generics was much larger. In the same year (1994), for example, IMS Health reported that as a proportion of pharmacies' total prescription drug acquisition costs, generics accounted for but 10%, while brands (and so-called branded generics) comprised the remaining 90%.[47] For retailers, therefore, generics have provided a relatively large source of profits – only 10% of costs, but 17% of revenues in 1994.

40. A just recently released study conducted by the Congressional Budget Office provides evidence of the continuing profitability to pharmacies of dispensing generic drugs. In 1997, 2000 and 2002, for example, while pharmacies' average acquisition costs of generic drugs were $4.30, $4.20 and $6.00, respectively, the amounts pharmacies were on average reimbursed by Medicaid for these generic drugs were $12.00, $16.10 and $19.90, implying absolute gross margins of $7.70, $12.00 and $13.80.[48] The CBO study went on to note that pharmacies' generic

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[45] The gap between average brand and average generic prescription price from retail continues to grow. In 2002, for example, the average prescription retail price to consumer was $81.68 for a brand and $25.13 for a generic, a 225% difference. See Healthcare Distribution Management Association, *2003 HDMA Industry Profile and Healthcare Factbook*, Table 205, p. 129.

[46] U. S. Congress, Congressional Budget Office, *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998. Available at http://www.cbo.gov/showdoc.cfm?index=655&sequence=0&from=1 .

[47] *The U.S. Pharmaceutical Market Year-in-Review 1995*, IMS International, Powerpoint presentation, p. 8, slide 23.

[48] U.S. Congressional Budget Office, Medicaid's Reimbursement to Pharmacies for Prescription Drugs, December 2004, Table 2, p. 4.

drug absolute gross margins had grown particularly rapidly for new multisource drugs, i.e. for drugs with initial generic entry after 1997.

41. The essential reason that brands and generics have such differing gross profitability profiles for retail pharmacies stems from retailers' differential buying power in these two segments. For any given prescription drug available from more than one generic manufacturer, the retail pharmacy buyer (particularly when organized into chains or other large buying groups) can stimulate price competition among the generic manufacturers. This occurs since the retail pharmacist can credibly threaten to substitute between any of the FDA-certified bioequivalent generic versions of a drug, choosing the particular version having the most favorable price comparison, thereby stimulating price competition among generic manufacturers. Moreover, commercial reimbursement from health plans/PBMs to pharmacies is typically the same, regardless of the generic manufacturer from whom the drug is purchased.

42. By contrast, in most cases the retail pharmacy cannot freely substitute between different patent-protected single source brands, unless explicit permission is first obtained from the prescribing physician. This inability to stimulate price competition among single-source brands means that when negotiating with branded manufacturer, the pharmacies have little bargaining power, and are essentially price takers.

43. In terms of the historic relationship between AWP and pharmacies' acquisition costs, and between AWP and pharmacies' reimbursement from third party payors, the picture for generics is considerably more complex and diverse than that for brands. Kolassa [1994a] paints a slightly different and potentially less benign picture for generic/multisource self-administered drugs:

> "This use of the AWP is even more pronounced with generic drugs. Many generic companies have taken advantage of this use of AWP by inflating their

> published AWPs substantially. For instance, in 1989 Geneva Generics increased some AWPs by as much as 1000% while decreasing their selling prices."[49]

44. After providing several examples in a table involving two nonsteroidal anti-inflammatory drugs both available in brand name and generic versions, Kolassa [1994a] characterizes the generic AWP phenomenon in a way strikingly similar to allegations made in the current litigation by Plaintiffs: [50]

> "This tactic, then, allows retailers to acquire a drug at a low cost, less than $5.00 per hundred, yet rely on a published AWP as high as $15.00 or more for their own pricing. It is not uncommon that the $25.00 retail price for a generic drug renders a gross profit well above $20.00 for the retailer."[51]

In his very similar 1997 textbook description of this phenomenon, Kolassa adds "It is also common for the AWP of a generic product to remain stable while the actual selling price declines."[52]

45. After providing a table documenting percentage differences between ex-factory prices and AWP ranging from 20% to 1,168%, Professor Kolassa concludes as follows, noting the heterogeneity in the pricing policies undertaken by generic manufacturers:

> "It is obvious that AWP is not an accurate measure of the prices manufacturers charge. It must also be noted that not all generic products will be priced similarly. Some, in fact, use the more traditional method of a 20% markup to reach an AWP. This can be a handicap for generic companies choosing this method because retailers often use the AWP as the starting point for many pricing decisions and an artificially high AWP provides the retailer with greater profits."[53]

46. The relationship between AWP, WAC and actual acquisition prices for generic self-administered drugs is considerably more complex, therefore, than that for single source branded

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[49] Kolassa [1994a], *supra*, p. 237.
[50] Indeed, in the paragraphs that follow, the quoted portions are virtually identical to unreferenced statements produced in *Plaintiffs' Amended Motion for Class Certification*, United States District Court, District of Massachusetts, In Re Pharmaceutical Industry Average Wholesale Price Litigation, M.D. L. No. 1456, Civil Action No. 01-12257-PBS, United States District Judge Patti B. Saris, December 17, 2004; see, for example, pp. 46-47.
[51] Kolassa [1994a], *supra*, p. 237.
[52] Kolassa [1997], *supra*, p. 37.
[53] Kolassa [1997], *supra*, pp. 37-38.

drugs. This complexity and variability has been known for quite some time. In 1992, for example, Henry Grabowski and John M. Vernon published a peer-reviewed article that examined generic entry patterns and pricing following 1984 passage of the Hatch-Waxman Act.[54] The measure of price used by Grabowski-Vernon was the average cost per unit paid by drugstores and hospitals for the most frequently consumed dosage size of each product.[55] Regarding generic price variability, Grabowski and Vernon report that:

> "One indication of the significant variability in generic prices is the fact that, in half of the eighteen generic products, the maximum price observed is over 50 percent greater than the minimum price, as measured one year after initial entry."[56]

For five of the eighteen products, the maximum price was in fact more than twice the minimum price.[57]

47. The Grabowski-Vernon study examined generic pricing patterns in the 1980s and early 1990s. The complexity and volatility of generic pricing persists. Plaintiffs' Expert Dr. Stephen Schondelmeyer reports that even in the more current context, the relationships among AWP, WAC and actual acquisition costs vary between single source brands, multisource brands, and multisource generics, and by class of trade.[58] In a recently jointly authored research report with Marian V. Wrobel, for example, he makes the following set of statements that highlight some of the differences between brand and generic self-administered drugs:

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[54] Henry G. Grabowski and John M. Vernon, "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act", *Journal of Law and Economics*, Vol. 35, October 1992, pp. 331-350.
[55] Grabowski and Vernon [1992], *supra*, p. 335.
[56] Grabowski and Vernon [1992], *supra*, p. 345.
[57] Grabowski and Vernon, *supra*, Table A2, p. 349.
[58] Ten classes of trade identified by Schondelmeyer and Wrobel are: chain pharmacy, mass merchant pharmacy, food & drug pharmacy, independent pharmacy, mail order pharmacy, health plan pharmacy, clinic & doctors' office; long term care pharmacy, hospital, and government facilities & other. See Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Abt Associates, Inc., Cambridge, MA, Prepared for Centers for Medicare and Medicaid Services, Contract #500-00-0049, August 30, 2004, p. 12.

"Most experts agree that AWP, or even the typical discounts to AWP, exceed actual acquisition costs for both pharmacies and physicians. This is particularly true for generic drugs."[59]

"The terms for describing drug prices have changed over the past four decades. New terms have emerged and old terms have developed new meanings. Careful definition of drug pricing terms is important to assure consistency and confidence in the prices reported and to assure propriety and accuracy when establishing payment and public policy."[60]

"In the past decade, WAC was a term that typically included adjustments for discounts, rebates, purchasing allowances, or other forms of economic consideration. {Footnote Not Repeated}. More recently, WAC has come to mean a list price before any form of price adjustment. WAC is closer to wholesaler's actual acquisition cost than is AWP. *However, due to different levels of discounts across drug products and specific classes of trade, the WAC does not generally have a reliable relationship to the actual acquisition cost. Within a specific class of trade, WAC may have a consistent relationship with the actual acquisition cost for single source brand name (patented and exclusivity protected brands) drug products, but not for innovator multiple source (off-patent brands) or non-innovator multiple source (generic) drug products.*"[61]

"A larger share of generic drugs, than of brand-name drugs, is sold direct from the manufacturer. *Because of different levels of discounts, the DP does not have a reliable relationship to the actual acquisition cost, in general, or for specific classes of trade.*"[62]

"When two or more generics enter the marketplace they typically compete on price with each other even though the brand name product usually does not compete on price. The first generic will typically enter the market at a list price (both AWP and WAC, if a WAC is reported) that is 10 to 30 percent below the originator brand price. Often the price competition among generic versions of a drug product will be reflected by one or two decreases in list prices (AWP and WAC) in the first six to twelve months after generic entry, but after that time it is rare to see generic list prices change and at some point in time the generic list prices for some drugs may even begin to rise again."[63,64]

"The relationship between list prices (AWP and WAC) is much less predictable for generic drugs than it is for brand name drugs. Some generic drug products will have AWPs that are the typical 20 to 25% above the WAC, but it is not unusual to see generic

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[59] Schondelmeyer and Wrobel [2004], *supra*, p. 7.
[60] Schondelmeyer and Wrobel [2004], *supra*, p. 13.
[61] Schondelmeyer and Wrobel [2004], *supra*, p. 14. Italics not in original..
[62] Schondelmeyer and Wrobel [2004], *supra*, p. 15. Italics not in original. DP (direct price) is defined by Schondelmeyer and Wrobel on the same page as "a *list price* used for *invoices between drug manufacturers and pharmacies or providers* " (italics in original text).
[63] Schondelmeyer and Wrobel [2004], *supra*, p. 17.
[64] Defendant's Expert Steven J. Young also notes that some generic manufacturers do not even have a WAC. See *Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, October 25, 2004, p. 64, Paragraph #188.

> *drug products with an AWP that is 50 to 100 percent, or more, above the WAC. Even more volatile is the relationship between the list prices (AWP or WAC) and actual acquisition costs for generics.* Generic firms often discount their actual net price to the pharmacy to compete with other generics, but they do not always reflect these discounts to lower AWP or WAC list prices. *Generic prices are also relatively volatile, because the market for generic drugs is effectively a commodity market.* Thus, AWP-based payment policy is much less accurate for these drugs than it is for the branded drugs."[65]

48. In terms of the final recommendations Schondelmeyer and Wrobel make to CMS regarding how both Medicaid and Medicare Part B might most reliably estimate actual acquisition costs of the drugs it reimburses providers, the first sentence in their Section "Recommendations and Directions for Further Work" is remarkably straightforward: "There is no simple method of estimating acquisition costs."[66]

49. One other issue distinguishing reimbursement for brands from generics regards dispensing fees. Recall that pharmacies are typically reimbursed by health plans/insurers/PBMs for drugs they dispense on the basis of a relatively simple formula, such as AWP – x% plus dispensing fee plus (occasionally) administrative fees.

50. A commonly held view is that dispensing fees received by pharmacies have tended to be lower than their actual dispensing costs, but that ingredient cost reimbursement has generally exceeded actual pharmacy acquisition costs, thereby offsetting the underrecovery of actual dispensing costs.

51. Reporting on themes emerging from an Expert Panel Meeting for the Medicaid and Medicare Drug Pricing Project held in January 2004, for example, Schondelmeyer and Wrobel report that in terms of Medicaid, there was "agreement that dispensing fees are lower than actual dispensing costs and that drug payment generally exceeds actual acquisition costs", and that "The spread in drug payment compensates for the low dispensing fees". Indeed, Schondelmeyer

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[65] Schondelmeyer and Wrobel [2004], *supra*, p. 18. Italics not in original.
[66] Schondelmeyer and Wrobel [2004], *supra*, p. 28.

and Wrobel apparently quote one expert verbatim, who stated "If it weren't for spread, pharmacies would be out of business."[67]

52. In the context of generic drugs, one widely understood reason third party payors have long been willing to allow pharmacies to enjoy a considerable "spread" on their generic drugs is that whenever a generic version of a drug is dispensed instead of its brand version, the third party payor typically saves a substantial mount of money (recall the earlier discussion on average brand prescription prices being considerably less than average generic prescription prices). Given that it enjoys these large savings, the third party payor is less likely to quibble over whether the pharmacy is pocketing a larger margin for generics than for brands. Recall also that from the vantage of third party payors, the generic share of total prescription costs for self-administered drugs is rather small, typically between 10% - 20%.

53. Defendant's Expert Robert P. Navarro describes his own experiences at the Physician Health Plan of Minnesota ("PHPM") and United Health Care ("UHC") in incenting pharmacies to dispense generically as follows:

> "I have found from my own experience that, in general, increasing generic dispensing has the potential to be one of the most important cost-containment strategies. At PHPM, we attempted to have approximately 50% or more of members' prescriptions dispensed generically. PBMs adopt such programs to encourage pharmacies to substitute generic for brand drugs, where therapeutically appropriate, and in some cases offer a guaranteed substitution rate. (Footnote Not Reproduced}. For example, Caremark has a performance program that rewards pharmacies for achieving certain levels of generic dispensing. {Footnote Not Reproduced}. At UHC, we also used pharmacist incentives (for example, paying a slightly higher dispensing fee for generics) to increase our generic dispensing rate for plans which had lower use of generic drugs."[68]

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[67] Schondelmeyer and Wrobel [2004], *supra*, Appendix B, p. B-2.
[68] *Declaration of Robert P. Navarro in Opposition to the Plaintiffs' Motion for Class Certification,* supra, p. 18, Paragraph #36.

54. A 2001 survey covering 468 employers and 15.5 million beneficiaries, conducted by the Pharmacy Benefit Management Institute and supported by the National Business Coalition on Health and the Employers' Managed Health Care Association, documents the extent to which plans employ differential brand-generic dispensing fees to incent pharmacies to dispense generic drugs more intensively:

> "Some employers deliberately pay a higher dispensing fee for generic drugs than for brand drugs as a way to encourage pharmacies to dispense more generics when possible. Approximately 32% of respondents pay a higher dispensing fee for generics. Generally, the generic dispensing fee is higher by $0.50 although some are as much as $1.00 higher."[69]

Since actual pharmacy dispensing costs are unlikely to differ materially between brands and generics, this differential generic-brand dispensing fee policy essentially amounts to a policy of third party payors deliberately allowing and indeed encouraging pharmacies' margins (inclusive of dispensing fee) to be larger for generics than they would otherwise be, and other things equal, to be larger for generics than for brands. In this sense, then, for generic drugs the dispensing fee and ingredient reimbursement are bundled together in ways that attempt to benefit both the third party payor and the pharmacy.[70]

55. A final issue distinguishing brand from generic self-administered drugs involves the formulae and contractual terms that are employed among health plans/insurers/employers, PBMs and pharmacies. Although almost all single source brand drugs are contractually reimbursed using AWP, generic/multisource drugs are more commonly reimbursed by commercial payors on the basis of what is called MAC (maximum allowable cost), or less frequently, MRA (maximum reimbursable amount).

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[69] *Takeda and Lilly Prescription Drug Benefit Cost and Plan Design Survey Report, 2001 Edition*, Tempe, AZ, The Pharmacy Benefit Management Institute, Inc., p. 25. Accessible via email at pbmi@pbmi.com.

[70] This point is also made by Defendants' Expert Steven J. Young. See *Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification* [2004], supra, p. 66, Paragraph #194; also see pp. 82-85, Paragraph # 231 – 237.

56. For example, Plaintiff's Expert Dr. Raymond Hartman reports that based on an analysis of 1999-2004 submitted claims to Harvard Pilgrim Health Care, while 98% of all branded drugs in what he calls "Set C" were reimbursed with reference to AWP, for the generic drug reimbursement claims only 37% reimbursed with reference to AWP, while 54% reimbursed with reference to a MAC definition.[71] Dr. Hartman notes that among those generic claims referencing AWP, a substantial portion "are composed of recently-launched generics, since the first several generics launched for any drug explicitly reference AWP."[72] This suggests that for Harvard Pilgrim Health Care, one should expect variability over time in the proportion of generic claims referencing AWP, with the proportion being larger shortly after important, frequently prescribed drugs lose patent expiration and generic entry takes place.

57. I note in passing that Dr. Hartman reports results from other insurers' claims data (University of Pittsburgh Medical Center – 1998 to 2004, and the Carpenters and Joiners Welfare Funds – 2001 to 2004) in which for apparently generic self-administered drugs, the proportion of claims referencing AWP varies considerably across time, insurer, and drug.[73] Based on this preliminary analysis, Dr. Hartman concludes that for generic drugs, "the majority of claims reference MAC."[74] For the same three drugs examined by Dr. Hartman, Defendant's Expert Steven J. Young reports that for Cigna RX, the proportion of new paid claims referencing WAC

[71] *Rebuttal Declaration of Dr. Raymond Hartman in Support of Plaintiff's Motion for Class Certification*, December 16, 2004, pp. 27-28 and Attachment B.2.a.
[72] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification* [2004], supra, p. 28.
[73] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification* [2004], supra, pp. 28-30, Attachments B-2b and B-2c.
[74] *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification* [2004], supra, p. 30.

is relatively uniform and high: albuterol 88.61% MAC, 4.14% AWP; griseofulvin 89.31% MAC, 1.54% AWP; and theophyline 86.10% MAC, 7.83% AWP.[75]

58. There is considerable documentation and discussion in this litigation concerning the relationship between AWP and MAC for multisource self-administered drugs reimbursed commercially. I shall not reference that extensive literature here. I do, however, want to stress two points. First, while some commercial payors apparently have over the years utilized MAC schedules taken from the Federal Upper Limits schedule published by CMS for Medicaid or from state-specific MAC schedules (these public sector MACs will be discussed further in the following sub-section of this report), a substantial portion of commercial payors have developed their own MAC lists and schedules. Second, commercial MAC lists and schedules are proprietary, and how they are constructed is proprietary information, about which little is publicly known.

59. For example, according to Defendant's Expert Steven J. Young:

> "PBMs and Health Plans consider their MAC lists to be highly confidential trade secrets. {Footnote Not Reproduced}. Most utilize proprietary methodologies for determining the MACs listed. In fact, many Payors agree to reimburse for generics at their PBM's MACs without knowing how those amounts were calculated. (Exhibits 17a and 17b)."[76]

Defendant's Expert Robert P. Navarro concurs, stating that "Many PBMs and health plans create their own MAC lists. Each uses different and typically proprietary methodologies."[77]

60. Plaintiff's Expert Dr. Raymond Hartman also notes that "Private TPPs and PBMs rely upon MAC rather than FUL", and that "Pharmacy Benefit Managers usually create their own MAC lists" (adding a footnote referencing an Express Script pro forma PBM contract that

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[75] *Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, October 25, 2004, Exhibit 17d.
[76] *Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification* [2004], supra, p. 66, Paragraph #193. Young discusses this further on pp. 66-67, Paragraph #s 194-198.
[77] *Declaration of Robert P. Navarro in Opposition to the Plaintiffs' Motion for Class Certification*, supra, p. 27, Paragraph # 52. Navarro's discussion of commercial MACs is found on pp. 26-29, Paragraph #s 50-56.

provides certain details concerning its definition of MAC). Regarding TPPs (third party payors), Dr. Hartman states, "However, how TPPs actually define MAC and the extent to which the TPPs strictly enforce MAC are unknown."[78]

C. AWP Discounts Attained by Government and Commercial Purchasers

61. In the US, the vast majority of drug prescriptions are paid for by private insurance or consumers' out of pocket payments; in 1998, these two non-government sources accounted for 79.3% of US drug spending. Nonetheless, through its various programs (e.g., Veterans' Administration, TriCare, Medicare, and especially Medicaid), the federal government has become a large volume purchaser; in 1998, Medicaid alone accounted for 17.1% of US drug spending.[79]

62. Over the years, the Office of Inspector General ("OIG") at the Department of Health and Human Services has conducted investigations and publicly issued a substantial number of reports comparing, among others: (i) Medicare and Medicaid reimbursement rates; (ii) Medicare/Medicaid reimbursement rates with prices paid by the Veterans' Administration; and (iii) Medicare/Medicaid reimbursement rates with commercial pharmacies' and providers' acquisition costs. The series of reports has covered physician- and other provider-administered drugs (chemotherapies, inhalation therapies, end stage renal disease drugs) covered through Medicare Part B benefits, as well as various self-administered drugs reimbursed by Medicaid. I summarize a sample of these reports in Attachment B. Other summaries are found in a National

[78] *Declaration of Raymond S. Hartman in Support of Plaintiff's Motion for Class Certification* [2004], supra, Attachment D, p. 13.
[79] U.S. Department of Health & Human Services, *Report to the President: Prescription Drug Coverage, Spending, Utilization, and Prices*, Washington DC, April 2000, Table 2-30, p. 89.

Health Policy Forum Issue Brief,[80] and in documents submitted by Plaintiffs' Expert Dr. Raymond S. Hartman,[81] and by Defendants' Expert Steven J. Young.[82]

63. Even though legislative and implementation guidelines mandated that Medicare reimburse based on the lesser of an estimated acquisition cost ("EAC"), "Usual & Customary" charges or some other "reasonable charge", for a variety of reasons the *de facto* benchmark for Medicare Part B reimbursement was 100% of AWP up until 1998, and then 95% of AWP until 2003.[83] A common finding from the OIG reports is that Medicare reimbursed at higher average prices than did Medicaid, and that the Medicaid reimbursement was less than AWP (often between 10% - 20% less for brands, and even larger reductions from AWP for generics). Medicare also typically paid higher average prices than did the Veterans' Administration, or chain and drug stores, each of which paid prices less than AWP.

64. A common feature of these OIG reports is that oftentimes they contained specific recommendations regarding alternative practices Medicare should consider employing, instead of continuing AWP-based reimbursement policies; in a number of cases, the report contains written responses to these recommendations from the Health Care Financing Administration ("HCFA", the predecessor agency to the Centers for Medicare and Medicaid Services, "CMS") or CMS.[84]

65. While it is not entirely clear why it has taken so very long for CMS to switch from AWP-based to an actual selling price (ASP)-based reimbursement, what is clear is that through

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[80] Dawn M. Gencarelli, "Average Wholesale Price: Is There a More Appropriate Pricing Mechanism?", National Health Policy Forum Issue Brief, No. 775/June 7, 2002, Washington DC: The George Washington University.
[81] *Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, Attachment D, pp. 2-9.
[82] *Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, In Re Pharmaceutical Industry Average Wholesale Price Litigation, MDL No. 1456, Relates to 01-CV-12257-PBS and 01-CV-339, Judge Patti B. Saris, pp. 54-63, Exhibits 7 and 16a.
[83] For further details and an historical discussion, see Medicare Payment Advisory Commission, *Report to the Congress: Variation and Innovation in Medicare*, ch. 9, "Medicare payments for outpatient drugs under Part B", June 2003.
[84] See, for example, Department of Health and Human Services, Office of Inspector General, *Medicaid Pharmacy – Additional Analysis of the Actual Acquisition Cost of Prescription Drug Products*, A-06-02-00041, September 2002.

these published reports and inter-agency public information exchanges, the fact that pharmacies' and providers' acquisition costs were typically less than AWP has long been made very visible and public. It has not been a secret, at least to active observers and health care industry participants.

66. Other government-sponsored studies and reports have also documented substantial discounts off the published AWP. For example, referring to a 1993 report issued by the General Accounting Office,[85] in 1996 the Congressional Budget Office noted that even private buyers obtained substantial discounts:

> "A recent General Accounting Office (GAO) survey found that four HMOs received an average discount off the published list price of 32 percent in 1990 and 34 percent in 1991 on their top 100 outpatient drugs."[86]

The Congressional Budget Office then elaborated on the extent to which AWP overstated actual acquisition costs, as follows:

> "The average wholesale price (AWP) is the published (list) price that manufacturers suggest wholesalers charge their customers. Wholesalers usually charge pharmacists a price that is lower than the AWP, which is the price that is most widely available in published form. In contrast, the average manufacturer price (AMP), used to calculated the Medicaid rebate, is not public information. The AMP is lower than the AWP since it is the average price paid by wholesalers. The Congressional Budget Office (CBO) has examined the relationship between the AMP and AWP to determine the equivalent discount off the AWP that a private purchaser must obtain before the Medicaid best-price provision applies.
>
> CBO examined the relationship between the AWP and AMP for 224 drug products that were the top-selling Medicaid drugs in 1993 (based on data collected by the Health Care Financing Administration for the Medicaid rebate program and the AWPs reported in *Redbook*). For that sample, the AMP averaged 80 percent of the AWP. Therefore, wholesalers paid on average 80 percent of the list price for those drugs. For 84 percent of the 224 drug products examined, the AMP fell between 75 percent and 85 percent of the

[85] General Accounting Office, *Medicaid: Changes in Drug Prices Paid by HMOs and Hospitals Since Enactment of Rebate Provisions*, GAO/HRD-93-43, January 1993.
[86] Congressional Budget Office, *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry*, Washington DC: CBO Papers, January 1996, p. 19.

> AWP. Given that the AMP is equal to 80 percent of the AWP on average, a discount of 32 percent off the AWP equals a discount of 15 percent off the AMP on average.[87]

67. The Department of Health and Human Services ("DHHS") has also highlighted the discrepancy between AWP and pharmacies' acquisition costs in its highly publicized Report to the President in April 2000. Here the DHHS explicitly stated:

> "A price that is commonly cited in the industry is the 'average wholesale price', or AWP. Despite what this name would suggest, the AWP is not the average of the amounts actually paid by retail pharmacies to wholesalers for a particular drug. Instead it is a published wholesale price or 'list price' suggested by the manufacturer of the drug. A wholesaler may sell specific drugs to all pharmacies at prices below the AWP, or may grant a general discount to certain pharmacies. Thus, although the AWP is often used by pharmacies as a cost basis for pricing purposes, it does not represent the actual cost to a retail pharmacy of acquiring the drug. It is merely a wholesale list price that can be used as a benchmark in comparing retail and wholesale prices."[88]

Hence, the fact that AWP should not be literally interpreted as an average price paid by pharmacies to wholesalers has long been widely publicized and communicated by various government organizations monitoring federal government reimbursements for prescription drugs. This has not been a secret.

68. Before leaving this section, I believe it is useful to digress briefly and distinguish Medicare/Medicaid reimbursement for generic/multisource self-administered drugs vs. that for brand/single source drugs. Federal Medicaid provisions do not dictate the precise amount a state may pay for a given drug, although they do place limits on what the federal government will match. In 1987 Medicaid regulations established the federal upper limit (FUL), which set limits on the amount that Medicaid could reimburse for drugs with three or more generic versions.

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[87] Congressional Budget Office [1996], supra, p. 20, Box 2, "Comparing the Average Manufacturer Price with the List Price". Italics in original. After the word *Redbook*, the CBO appended a footnote 1, containing the statement: "Medical Economics Data, 1994 *Redbook* (Montvale, N.J.: MED, 1994)."

[88] U. S. Department of Health and Human Services, Report to the President [2000], *supra*, p. 101. At the end of this paragraph, the original text appends a footnote, stating "In establishing upper payment limits for state Medicaid programs, HCFA assumes that AWP overstates actual acquisition costs by 10 to 20 percent. (State Medicaid Manual, sec. 6305.1)"

Over the years the way in which FUL has been established has changed. States may set their own payment ceilings for these drugs, provided they do not exceed the federal payment limit.[89] Many state Medicaid programs have established their own lists of maximum reimbursement prices for generic self-administered drugs, which are typically also called MAC (maximum allowable cost) programs.[90] These state-specific programs also establish dispensing fee and patient copayment policies, which vary considerably among the states.[91] As a general rule, the state-specific lists typically include more drugs, list newly available generic drugs more quickly, and establish more aggressive (i.e., lower) reimbursements than does the FUL list.[92]

69. For example, a recent study by the Office of the Inspector General found that of the top 200 multisource drugs (based on retail sales for the year 2001) dispensed in the US, 90 drug products met the established criteria for inclusion, but in fact were not included on the FUL list in 2001.[93] As part of the Omnibus Budget Reconciliation Act of 1990, Congress mandated that drug manufacturers sign a rebate agreement with the federal government in order to receive payment for outpatient prescription drugs provided to Medicaid beneficiaries. Although there can be some waivers, in exchange states must cover all Food and Drug Administration-approved prescription drug products manufactured by a company that has signed a rebate agreement.[94] For generic manufacturers, the rebate is 11 percent of the product's Average Manufacturer's Price

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[89] See Dawn M. Gencarelli, "Average Wholesale Price for Prescription Drugs: Is There a More Appropriate Pricing Mechanism?", *National Health Policy Forum*, Issue Brief No. 775, June 7, 2002, Washington DC: George Washington University, and the references cited therein for further details.
[90] For a description of state-specific MAC programs in 2003, see National Pharmaceutical Council, *Pharmaceutical Benefits 2003*, p. 4-42.
[91] National Pharmaceutical Council, *Pharmaceutical Benefits 2003*, p. 4-41.
[92] See, for example, Richard G. Abramson, Catherine A. Harrington, Raad Missmar, Susan P. Li and Daniel N. Mendelson, "Generic Drug Cost Containment in Medicaid: Lessons from Five State MAC Programs," *Health Care Financing Review*, 25(3), Spring 2004, pp. 25-34.
[93] Department of Health and Human Services, Office of Inspector General, *Omission of Drugs From The Federal Upper Limit List in 2001*, OEI-03-02-00670, February 2004.
[94] Dawn Gencarelli [2002], *supra*, p. 8.

("AMP"), while for branded, single source drugs, the rebate formula is more complex.[95] For both generics and brands, the AMP is computed as follows:

> "AMP is the average price paid to manufacturers by wholesalers (after all discounts, including manufacturer rebates) for a particular dosage form and strength of a prescription drug distributed solely to the retail pharmacy class of trade. The AMP is not a published price. It is calculated by the manufacturer and submitted to CMS for purposes of calculating the Medicaid rebate. The government holds it confidentially to protect the proprietary nature of the deals negotiated between manufacturers and their best customers. AMP is subject to government audits, making manufacturers accountable for its accuracy."[96]

70. Over the years the OIG has issued a number of reports documenting the acquisition costs to pharmacies of generic drugs dispensed to Medicaid recipients. For calendar year 1994, the OIG estimated that the average discount off AWP at which pharmacies purchased generic drugs was 42.45%; by 1999, this average discount off AWP for generic drugs increased to 65.93% (excluding non-traditional pharmacies, defined as nursing home pharmacies, hospital pharmacies, home IV, etc.). In both years these national averages also masked modest differences by class of trade and geography. Specifically, the 1994 (1999) averages discount off AWP for rural-chain pharmacies was 47.51% (64.39%); for rural-independent pharmacies it was 47.38% (66.64%); for urban-chain pharmacies it was 37.61% (66.97%); and for urban-independent pharmacies it was 46.72% (63.70%). The largest average discounts off AWP were obtained by the non-traditional pharmacies (defined above) – 57.70% in 1994 and 67.07% in 1999.[97]

71. A subsequent OIG analysis of the 1999 data revealed that if the drugs were disaggregated in a slightly different way, while certain patterns became apparent, considerable

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[95] Dawn Gencarelli [2002], *supra*, pp. 8-9.
[96] Dawn Gencarelli [2002], *supra*, pp. 8-9. It is my understanding that AMP also includes drugs dispensed via mail order to commercial health plans/insurers/PBMs.
[97] Department of Health and Human Services, Office of Inspector General, *Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products*, A-06-01-00053, March 2002, p. 4.

heterogeneity persisted. Specifically, for single source drugs, the average discount off AWP was 17.2%, although the range was from 13% to more than 22%, with modest variability across class of trade, rural vs. urban, and by state. For multiple source drugs without FULs (including both brands and some generics), the average discount (excluding non-traditional pharmacies) was 42.03%, masking more substantial differences between urban-independent (37.10%) and urban-chain (45.56) average discounts. However, for multiple source drugs with FULs (primarily generics), the average discounts off AWP were much larger, averaging 72.13% (excluding non-traditional pharmacies). Again, these averages concealed considerable heterogeneity in average discounts by class of trade, rural vs. urban, and by state.[98]

72. Another study undertaken by a different federal agency, the Congressional Budget Office, and released just recently in December 2004, focuses on pharmacy markups ("the dollar difference between the total amount that Medicaid pays the pharmacy for each prescription and the amount that the pharmacy or wholesaler pays the manufacturer for the drug") between 1997 and 2002.[99] Since I have discussed this paper earlier in this report, I will not elaborate on it further here, other than to repeat its central findings, that "Between 19977 and 2002, by CBO's estimates, the average markup increased by nearly 60 percent – rising from $8.70 to $13.80 per prescription, or by about 9.7% per year", and that the markup depended not only on brand vs. generic, but also on the vintage of the generic (continuing generic, new generic drugs introduced by 2000, and new generic drugs introduced by 2002). The CBO summarized this finding as follows::

[98] Department of Health and Human Services, Office of Inspector General, *Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products*, A-06-02-00041, September 2002, various appendices.
[99] Congressional Budget Office, *Medicaid's Reimbursements to Pharmacies for Prescription Drugs*, December 2004, p. 1.

> "Much of the increase in the average markup was attributable to the use of relatively new generic drugs. For generic drugs that came on the market between 1997 and 2002, Medicaid reimbursed pharmacies an average of about $46 per prescription in 2002, of which only about $14 went for the purchase of the drug itself. Pharmacies and wholesalers retained the remainder, or markup, of about $32 per prescription."[100]

73. I conclude, therefore, the fact that AWP very substantially overstates pharmacies' actual acquisition costs for generic self-administered drugs has long been publicly available information, as has the fact that the extent of overstatement has been growing over time. There is also substantial, perhaps growing, heterogeneity in the extent of discounting off AWP among different pharmacy classes of trade, rural vs. urban, by state, and by whether the multisource drug was on the FUL list.

D. Why the Continued Confusion Concerning What is AWP?

74. Despite the fact that apparently most knowledgeable industry observers have long understood and taken into account in their decision-making that no one (except perhaps Medicare and the cash-paying retail customer) pays a price for branded drugs as high as AWP,[101] this knowledge is not universally held, and some confusion still remains. Depositions in this litigation document this confusion.

75. In the attachments accompanying *Plaintiffs' Reply Memorandum in Support of Class Certification* summarizing testimony from individuals deposed in this litigation, the record reveals a number of deponents testified in a way indicating they clearly understood that WAC was less than AWP and that pharmacies typically acquired drugs at prices considerably less than

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[100] Congressional Budget Office, *Medicaid's ts to Pharmacies for Prescription Drugs*, December 2004, p. 1.

[101] Interestingly, in the simulation model of the PBM industry used by Banc of America Securities, it is stated that " we assume AWP to be equal to average retail price (coincidentally this is often, approximately the case)". In particular, AWP is set equal to "Listed retail price". See Banc of America Securities, *Pharmacy Benefit Managers: Keeping a Lid on Drug Costs*, Health Care Technology and Distribution Industry Overview, February 2002, Figure 12, p. 21.

AWP; see, for example, testimony from deponents Gregory Madsen from Caremark;[102] Rena Maxwell from University of Pittsburgh Medical Center;[103] Bob Schultz from Blue Cross Blue Shield of Wyoming;[104] Carol Sidwell from John Deere, Inc.;[105] and Dale Kramer from Kaiser Permanente.[106] On the other hand, testimony from a number of other deposed individuals indicated they interpreted AWP more literally, as some average of wholesale prices charged by wholesalers and/or paid for by pharmacies to wholesalers, or prices paid by wholesalers to manufacturers; see, for example, the testimony by Linda Montefort from Empire Blue Cross Blue Shield of New York;[107] David Thomas from Three Rivers Health;[108] Dan Dragalin from Multiplan, Inc.;[109] Richard Francis from Harvard Pilgrim Health Care;[110] and Daniel Ryan from the United Food and Commercial Workers.[111]

76. Plaintiffs' Counsel have even noted that in the glossary of the 1999 textbook authored by Defendants' Expert Robert P. Navarro, the following definition is given:

> "AWP – average wholesale price; the standard charge for a pharmacy item; derived by taking the average cost of the item to a pharmacy as charged by a large representation of pharmacy wholesale suppliers (for items not otherwise being sold at a discount)."[112]

On the other hand, Plaintiffs' Expert Dr. Stephen Schondelmeyer has previously written that while AWP is not literally the average price paid by pharmacies for prescription drugs, the

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[102] *Plaintiffs' Appendix of Summary Charts in Support of Class Certification*, December 16, 2004, Exhibit 1a, p. 8. Hereafter I will call this set of deposition summaries as "Plaintiffs' Appendix 1a [2004]".
[103] Plaintiffs' Appendix 1a [2004], *supra*, pp. 9-10.
[104] Plaintiffs' Appendix 1a [2004], *supra*, pp. 12-13.
[105] Plaintiffs' Appendix 1a [2004], *supra*, p. 13.
[106] *Plaintiffs' Appendix of Summary Charts in Support of Class Certification*, December 16, 2004, Exhibit 1b, pp. 13-16. Hereafter I will call this set of deposition summaries as "Plaintiffs' Appendix 1b [2004]".
[107] Plaintiffs' Appendix 1a [2004], *supra*, pp. 10-11.
[108] Plaintiffs' Appendix 1a [2004], *supra*, p. 15.
[109] *Plaintiffs' Appendix of Summary Charts in Support of Class Certification*, December 16, 2004, Exhibit 1c, p. 1. Hereafter I will call this set of deposition summaries as "Plaintiffs' Appendix 1c [2004]".
[110] Plaintiffs' Appendix 1c [2004], pp. 1-2.
[111] Plaintiffs' Appendix 1c [2004], p. 3.
[112] As cited in Class Plaintiffs Memorandum in Support of Their Motion to Strike Portions of the Declaration of Robert P. Navarro, , In Re Pharmaceutical Industry Average Wholesale Price Litigation, MDL No. 1456, Relates to 01-CV-12257-PBS, December 17, 2004.

relationship between these list prices and actual acquisition costs is "constant" over time. Specifically, when introducing the National Association of Chain Drug Stores PRIME price index for the "Top 200 drugs by 1991 dollar volume sold through community pharmacies" based on Medi-Span list price data, he wrote:

> "Even though the AWP does not represent the actual price paid by pharmacies for drug products, there is typically a constant relationship between these list prices and the actual acquisition cost for most pharmacies. Manufacturers nearly always raise their list prices and their actual transaction prices to traditional community pharmacies at the same rate. Manufacturers' price change patterns have been monitored to identify and adjust for those cases where list prices and direct prices appear to have changed at a different rate."[113]

77. Part of the continued confusion apparently emanates from statements made by First DataBank, a publisher of AWP prices. For example, in the September 1991 issue of a First DataBank's publication, in an article entitled "Understanding AWP", the following definition appears:

> "AWP represents an average price which a wholesaler would charge a pharmacy for a particular product. The operative word is average. AWP never means that every purchase of that product will be exactly at that price. There are many factors involved in pricing at the wholesale level which can modify the prices charged even among the same wholesaler. AWP was developed because there had to be some price which all parties could agree upon if machine processing was to be possible."[114]

78. Essentially the same definition of AWP is given today. For example, the American Society of Consultant Pharmacists' website contains an "AWP Briefing Room" backgrounder on "AWP Changes for intravenous, inhalant and injectable Medications" in which information is

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[113] Stephen W. Schondelmeyer, "The NACDS *PRIME* Index: Tracking Changes in Drug Prices", prepared for National Association of Chain Drug Stores, August 14, 1992, pp. 1-2. Italics in original. I note that elsewhere Professor Schondelmeyer has stated that the meaning of price terms have changed over time. See, for example, Schondelmeyer and Wrobel [2004], *supra*, p. 13.

[114] *First DataBank Monthly Interest*, "Understanding AWP", Vol. 6, No. 9, September 1991, p. 1. FDB-AWP 28850-28852.

given "on how AWP is calculated" by First DataBank ("FDB"). This internet search process yielded the following statement:

> "I have many conversations regarding what is 'AWP' and how does FDB determine it. There is much folklore and misunderstanding as to the determination of AWP and where we get the data.
>
> AWP is the average **wholesale** price. That is, AWP is the average of the prices charged by the national drug wholesalers for a given product (NDC). The operative word is **average**. AWP was developed to provide a price that all parties could agree upon for electronic processing to be possible.
>
> In order to determine the AWP, First DataBank surveys national wholesalers to ascertain what they use as a price basis in their AWP files. We contact the wholesalers to determine what the markup should be for a new company or to confirm that the markup that we are applying is current. A survey may be performed on a single NDC number or for a manufacturer's entire line of products. In either case, each national wholesaler is surveyed on a number of products from each manufacturer.
>
> The number of surveys performed is increasing. First DataBank surveys drug wholesalers that represent over two-thirds of the wholesaler total dollar volume. The markup that First DataBank utilizes is representative of wholesalers on a national level. Because individual wholesalers may mark up each manufacturer differently, a weighted average, not a consensus average, is calculated. That is, the market share held by the wholesalers surveyed affects the markup proportionally. Wholesalers with higher drug dollar volumes have more weight in the determination of the final markup. Thus, a higher degree of certainty is achieved. We also consider the manufacturer's suggested wholesale price (SWP) in our determination."[115]

79. At the First DataBank website "Frequently Asked Questions", under the question "How does First DataBank determine the Net Wholesale Price, Direct Price and Blue Book AWP as published in NDDF Plus and PriceProbe?", the following statement was retrieved in January 2005:

> "The Net Wholesale Price (also known as the wholesale acquisition cost or wholesale price) represents the manufacturer's published price for a drug product

[115] *Average Wholesale Price*, as found on the American Society of Consultant Pharmacists website, with a note this was last modified on 06/05/00. Online at http://www.ascp.com/public/ga/awp/awpinfo.shtml, accessed 1/22/2005. Boldface in original.

> to wholesalers. The Direct Price represents the manufacturer's published price for a drug product to non-wholesalers.
>
> First DataBank defines the 'Blue Book Average Wholesale Price,' which is commonly used as AWP, as the average of prices published by wholesalers to their customers for a given product. To determine Blue Book AWP, First DataBank typically identifies the Net Wholesale Price (or in some cases, the Direct Price) of a product, and then surveys the full-line national wholesalers to determine the average mark up applied to the manufacturer's line of products or a specific product. Such surveys may be conducted at the request of our customers or when a change in the marketplace occurs (such as a merger of manufacturers) which might occasion a change in prices. First DataBank does not include regional wholesalers or specialty distributors in its survey.
>
> First DataBank's Blue Book AWP is not intended to represent the wholesale price suggested by the manufacturer. Instead, First DataBank reports the manufacturer's suggested wholesale prices in a separate data field known as 'SWP.' In some cases, if manufacturers do not sell to wholesalers or if wholesalers agree with the manufacturer's suggested wholesale price, the Blue Book AWP and SWP may be the same.[116]

80. Two further examples illustrate factors contributing to the continuing confusion and ambiguity concerning AWP. First, in the 2000 edition of Novartis' Pharmacy Benefit Report, an industry trade publication, the glossary defines AWP as follows:

> "Average wholesale price (AWP) -- A published suggested wholesale price for a drug, based on the average cost of the drug to a pharmacy from a representative sample of drug wholesalers. There are many AWPs available within the industry, AWP is often used by pharmacies to price prescriptions. Health plans also use AWP – usually discounted – as the basis for reimbursement of covered medications."[117]

Second, a more recent widely cited California HealthCare Foundation report (prepared by a well-known health care consulting firm) contains the following glossary definition:

> "Average wholesale price (AWP) – A list of benchmark prices set by averaging across the spectrum of prices charged to pharmacies by wholesalers for both brand-name and generic drugs. The current list price is published in recognized

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[116] First DataBank "Frequently Asked Questions". Accessed online at http://www.firstdatabank.com/customer_support/faqs, on January 20, 2005.

[117] *Novartis Pharmacy Benefit Report: Facts & Figures*, 2000 Edition, East Hanover, NJ, Novartis Pharmaceuticals Corporation, p. 43.

sources, including Medi-Span, FirstData Bank and its supplements, and Medical Economics' Red Book."[118]

81. It appears, therefore, that inconsistent and ambiguous information exists even currently concerning what type of price AWP measures. The continuing confusion is real and understandable.

E. Other Uses of AWP

82. In the previous paragraphs I have considered AWP in the context of sending signals on the structure of prices for self-administered drugs to potential purchasers. Several other uses of AWP exist, and in some cases these uses are likely to constrain the extent to which manufacturers face incentives to "artificially inflate" their AWPs. In other cases, published guidelines recommend use of AWP, and even the FDA suggests use of AWP. I provide examples in Attachment C.

F. Physician-Administered Drugs: Medicare Part B and Private Coverage

83. To this point, I have focused attention almost exclusively on self-administered single and multisource drugs. I have done so in part because I infer that the potential size of the class consisting of AWPID self-administered drugs is likely to be much larger than that for AWPID physician-administered drugs. An additional reason for beginning with self-administered drugs is that their distribution and benefit management differs markedly from that for physician-administered drugs, and combining the two into one discussion could mask their differences.

84. Some drugs are manufactured in both self-administered (e.g., tablets and capsules) and physician-administered (e.g., injectable) formulations. Even some injectable formulations can be either self-administered or physician-administered, depending on the health of and training

[118] California HealthCare Foundation, *Navigating the Pharmacy Benefits Marketplace*, Prepared by Mercer Human Resource Consulting, January 2003, p. 39. Available online at http://www.chcf.org/documents/hospitals/NavPharmBenefits.pdf.

received by the patient. For the moment, I will follow the CMS convention that a self-administered drug is one that is administered by the patient more than 50 percent of the time.[119] By physician-administered, I do not necessarily imply that the attending physician actually performed the procedure, but rather that it was done in a physician's office (perhaps by a nurse or nurse's aide) and billed by the physician.

85. By way of background, under Part B of Medicare, Medicare covers certain drugs administered in physician offices, used as part of durable medical equipment or infusion devices, as well as some oral drugs used following organ transplants. Medicare-covered outpatient drugs are mainly used in cancer treatment, dialysis, organ transplantation, and hemophilia.[120] Medicare reimburses physicians for 80% of the charges, while patients' coinsurance payments comprise the remaining 20%, once they meet the annual Part B $100 deductible; often the patients' coinsurance portion is supplemented by additional "MediGap" or other "wrap around" insurance policies that cover all or portions of the 20% coinsurance payments..

86. In 1999, Medicare and its beneficiaries spent $3.9 billion on prescription drugs; with a 20% patient coinsurance ratio, beneficiary payments were less than $1 billion, less than 1% of total drug expenditures in the U.S. at that time;[121] in 2000 the Medicare Part B expenditure grew by about 25% to $5.09 billion, by another 25% in 2001 to $6.41, and in 2002 it was projected to grow by 33% to $8.5 billion, comprising about 3% of total Medicare spending.[122] While in levels and share still relatively small, the Medicare Part B growth in drug expenditures has been very substantial, and has therefore attracted considerable attention.

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[119] Dawn Gencarelli [2002], *supra*, fn. 6, p. 16.
[120] "Medicare payments for outpatient drugs under Part B", ch. 9 in Medicare Payment Advisory Commission, *Report to Congress: Variation and Innovation in Medicare*, June 2003, p. 150. Hereafter I will refer to this chapter as MedPAC [2003].
[121] *Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, October 25, 2004, p. 55, Paragraph 158. A slightly larger $4.09 billion Medicare drug expenditure is reported in MedPAC [2003], *supra*, Figure 9-2, p. 154.
[122] MedPAC [2003], *supra*, p. 154.

87. Spending for Part B drugs is highly concentrated, with the top 35 drugs accounting for almost 90% of drug spending, and three specialties – hematology oncology, medical oncology and urology – accounting for more than half of the total billing in 2001. A substantial portion of these Part B drugs represent novel and recently FDA-approved treatments. Of the top twenty drugs covered by Medicare in 2001, seven had received FDA approval in 1996 or later.[123]

88. All together, Medicare covers about 450 drugs under its Part B benefits. Many of these drugs are not generally available through retail pharmacies, but are provided by physicians in their offices or through pharmacy suppliers that provide drugs used with durable medical equipment. According to MedPAC, they include:

- drugs not self-administered and furnished incidental to a physicians' service, such as prostate cancer drugs;
- certain cancer and antinausea drugs available in pill form;
- blood clotting factor;
- immunosuppressive drugs used following organ transplants;
- erythropoietin used to treat anemia in end-stage renal disease patients and cancer patients;
- drugs used as part of durable medical equipment or infusion devices like the albuterol used in nebulizers for asthma and other pulmonary diseases; and
- osteoporosis drugs provided to certain beneficiaries by home health agencies.[124]

89. This set of outpatient drugs contains many brand name drugs and biologicals for which no effective therapeutic competition exists, and thus they can be very expensive. In 2001, physician claims accounted for more than 80% of total Medicare expenditures for outpatient

[123] MedPAC [2003], *supra*, p. 150.
[124] MedPAC [2003], *supra*, pp. 150-151,

drugs. For some specialties, payments for Part B drugs represent a large portion of total Medicare payments: 72% of all Medicare payments to hematology oncologists and medical oncologists were for Part B drugs in 2001, while 64%, 43% and 31% of payments to hematologists, urologists and rheumatologists, respectively, were for Part B covered drugs.[125] Notably, about half of all cancer patients are covered by Medicare.[126]

90. A large portion of these physician-administered Part B drugs are frequently referred to as "specialty pharmacy" products. An industry trade study notes that while there are many definitions of specialty pharmacy products, the concept broadly encompasses:

- products used to treat chronic, high-cost, or rare diseases;
- pharmaceutical or biological products administered via any non-oral means (e.g., infusion, injection, transdermal);
- products manufactured with a biological basis (e.g., blood products, insulin, etc.);
- any products administered in a non-hospital setting, including physician office, specialty clinic or patient's home;
- injectable and infusion therapies delivered in a non-hospital setting;
- high-cost ($5,000 and up per patient per year) therapies; and
- therapies that require complex care, including special handling, patient education and continuous monitoring.[127]

Pharmacies specializing in selling specialty pharmacy products are known as specialty pharmacy providers or specialty pharmacies.[128]

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[125] MedPAC [2003], *supra*, p. 151.
[126] American Society of Clinical Oncology, *Reform of the Medicare Payment Methods for Cancer Chemotherapy*, Alexandria, VA, May 2001, p. 2.
[127] Atlantic Information Services, Inc., *Specialty Pharmacy: Stakeholders, Strategies and Markets*, edited by Susan Namovicz-Peat, Washington DC, 2003, p. 1. Hereafter I refer to this document as "AIS [2003]".
[128] AIS [2003], *supra*, p. 1.

91. Over the years Congress has authorized expanded Part B coverage; decisions by CMS and local Medicare carriers determine the specific drug products eligible for reimbursement, occasionally leading to significant regional differences in coverage.[129]

92. According to Defendants' Expert Steven J. Young, Medicare's pre-1992 reimbursement policy involved paying for physician services and drugs on a "reasonable charge" methodology, reimbursing the physicians' entire billed charge as long as it was deemed reasonable by the local Medicare carrier. In particular, that reimbursement policy resulted in physicians earning the difference between what they paid for the drugs and the AWP at which Medicare reimbursed them.[130] Apparently in June 1991, HCFA proposed that Medicare Carriers base payment for drugs at 85% of AWP, based in part on an OIG report that pharmacies were obtaining on average a discount of 15% off AWP, after making the assumption that physicians likely paid no more than pharmacists.[131]

93. In opposing this policy, some physician specialties argued that if reimbursed at only 85% of AWP, the ancillary costs of providing these Part B drug services would not be fully recouped. According to the American Society of Clinical Oncologists ("ASCO"), for example, increasingly in the 1980s chemotherapy treatments were moving from the hospital to outpatient departments and physician offices, aided in part by the introduction of new antinausea agents that mitigated the troublesome side effects of many toxic chemotherapies. With the vast majority of chemotherapy treatments occurring in outpatient settings, such as physicians' offices, oncologists argued that reimbursing them at less than AWP would not cover chemotherapy administration costs, such as mixing powdered toxic chemotherapies in an appropriate solution,

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[129] MedPAC [2003], *supra*, p. 151. Examples of Congressional expansion of benefits are given on p. 152 of that document.
[130] *Declaration of Steven J. Young in Opposition to the Plaintiff's Motion for Class Certification*, October 25, 2004, p. 55, Paragraph 160.
[131] American Society of Clinical Oncologists [2001], *supra*, p. 7.